IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant	:	Andrieu et al.
App. No	:	10/550,297
Filed	:	September 21, 2005
For	:	INTRAPARIETAL AORTIC VALVE REINFORCEMENT DEVICE AND REINFORCED AORTIC VALVE
Examiner	:	Ann M. Schillinger
Art Unit	:	3774
Conf. No.	:	1931

DECLARATION OF DR. NORMAN JAFFE UNDER 37 C.F.R. §1.132

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

I, Norman Jaffe, Ph.D., hereby declare as follows:

1. This Declaration is being submitted to establish that if the device of Moe et al. were modified to employ biological tissue rather than the biocompatible polymer taught by this reference, the resulting device would be expected to fail as a result of erosion of the leaflet tissue resulting from contact between the tissue and the stent structure.

2. I have a Ph.D. in medicine from the University of Florida and am an expert in the field of cardiovascular valve repair and replacement, as well as in the development of bioprosthetic heart valves. For the past 35 years I have worked in various capacities in the design, development, and clinical evaluation of bioprosthetic medical devices. In particular, my work has focused on cardiovascular bioprosthetic devices. Over the course of my career, I have

developed three bioprosthetic heart valves which have been used clinically throughout the world. In addition, I am an inventor on various patents in the field of bioprosthetic valve fabrication.

3. I am a paid consultant to Leman Cardiovascular S.A., which is the assignee of the above-referenced patent application (the '297 application).

4. I am also the President and CFO of Hancock Jaffe Laboratories, a Delaware corporation that has a research and development agreement with Leman Cardiovascular S.A.

5. I have read and understand the specification and claims of the '297 application. I understand that the claims concern a bioprosthetic valve comprising an aortic valve obtained from an animal, and an intraparietal reinforcement device comprising a rod implanted in the tubular outer wall of the aortic valve.

6. I am familiar with the course of prosecution of the '297 application, including the Office Action issued on October 30, 2008, in which U.S. Publication No. 2003/0023302 (Moe et al.) was discussed. I understand that the Examiner asserts that the currently pending claims are anticipated by the Moe et al. reference.

7. The Moe et al. reference discloses a polymer valve, with a support stent having a sewing cuff assembly disposed between two layers of synthetic material. The Moe et al. reference does not disclose a "biological prosthesis comprising an aortic valve obtained from an animal."

8. At the time the above-identified application was filed, one of skill in the art would not consider replacing the biocompatible polymer described in the Moe et al. reference with tissue obtained from the aortic valve of an animal. In particular, if tissue from the aortic valve of an animal were substituted for the biocompatible polymer disclosed in Moe et al., the biological tissue would contact the stent structure of the Moe et al. device. Repeated contact between the stent structure of Moe et al. and the biological tissue during opening and closing of the valve would be expected to result in failure of the device due to erosion of the leaflet tissue.

9. I declare further that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true. I declare that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Respectfully submitted,

Dated: 12/23/2008

By: Dr. Norman Jaffe

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